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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,174	06/27/2001	William M. Blackshear JR.		5327

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EXAMINER	
RINES, ROBERT D	
ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
03/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/894,174	BLACKSHEAR ET AL.	
	Examiner	Art Unit	
	R. David RINES	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 December 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 24 December 2008. Claims 1-16 have been cancelled. Claim 17 is pending.

Claim Rejections - 35 USC § 112/ Claim Rejections - 35 USC § 101

[2] The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[3] 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requires of this title.

[4] Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Under 35 U.S.C. 101, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter. Claim 17 is unclear as to which statutory class of invention the claimed invention is directed.

As designated by the preamble of the claim, the claim appears to be directed to a system, i.e., machine or apparatus. However, the body of the claim recites a series of method steps but fails to recite any specific system components or elements such as a computer or server, i.e., hardware. As the body of the claim recites a method, for purposes of examination, Examiner assumes Applicant intends to claim a method of "classification and management". However, appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requires of this title.

[5] Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Under the statute, the claimed invention must fall into one of the four recognized statutory classes of invention, namely, a process (or method); a machine (or system); an article of manufacture; or a composition of matter. The latter three categories define "things" or "products" while a process consists of a series of steps or acts to be performed. For purposes of determining whether a process is eligible for patent under 35 U.S.C 101, a process has been given specialized, limited meaning by the courts.

Under the guidance of Supreme Court precedent and recent Federal Circuit decisions, in order for a process to be considered eligible for patent under 35 U.S.C. 101, the process must (1) be tied to another statutory class or (2) transform underlying subject matter to a different state or thing. If neither of these requirements is met by the claim, the process is not a patent eligible process under 35 U.S.C. 101 and is accordingly rejected as being directed to non-statutory subject matter.

Claim 17 recites a series of method steps directed to "A classification and management system for patient with lower extremity arterial occlusive disease…". The method steps presented in the body of the claim fail to positively recite the use of a machine, article of manufacture, or a composition of matter in achieving the desired result. As presently constructed, the recited method steps can be accomplished purely by mental processing and are therefore not specifically enabled by another recognized statutory class of invention. Accordingly, claim 17 is rejected because it is directed to non-statutory subject matter under 35 U.S.C 101.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[6] Claims 1-16 have been cancelled.

[7] Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Crutchfield (United States Patent #6,699,193).

As per claim 17, Crutchfield et al. disclose a method for the management and treatment of patients at risk of complications of arterial occlusive disease comprising the steps of: examining a patient at a healthcare facility with lower extremity arterial occlusion disease (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39), collecting patient data including physically observable conditions of the patient's lower extremities and noninvasive arterial pressure and blood flow data (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39), recording the collected patient data (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting said collected patient data to an evaluating authority (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), comparing said

collected patient data against a medically accepted set of disease specific criteria at the evaluating authority to classify patients "potentially at risk" and those patients "not at risk" of developing complications of arterial occlusive disease (Crutchfield et al.; col. 9, lines 25-50), transmitting said preliminary classification to the healthcare facility (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), referring those patients classified as "potentially at risk" of arterial of arterial occlusive disease to an accredited laboratory for noninvasive vascular evaluation (Crutchfield et al.; col. 9, lines 14-52), evaluating those "potentially at risk" patients at the accredited laboratory against medically accepted criteria (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), recording the results of said noninvasive vascular evaluation at the accredited laboratory (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting said recorded results to the evaluating authority for final classification (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), classifying each patient at the evaluating authority against medically accepted criteria as "at risk" or "not at risk" of developing arterial occlusive disease (Crutchfield et al.; col. 9, lines 40-52 and col. 10, lines 6-20), transmitting said "at risk" or "not at risk" patient final classification to the healthcare facility (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), recording said "at risk" or "not at risk" patient final classification at the healthcare facility (Crutchfield et al.; col. 9, lines 24-29 and lines 30-39, col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), referring patient having a final classification of "at risk" for critical ischemia with associated extremity lesions and patients with and patient with noninvasive evidence of severe ischemia to a vascular surgery facility for vascular surgical assessment to determine whether revascularization

is necessary (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), assessing such "at risk" patients against medically accepted criteria as "clinical indication for operation" or "no indication for operation" at the vascular surgery facility (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), electing revascularization and periodic management system evaluation at the healthcare facility or routing wound care and periodic revaluation at the healthcare facility by patients assessed as "clinical indication for operation" (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), monitoring patients assessed as “no indication for operation” by the healthcare facility with increased precautions to monitor for detection of any visible deterioration of the patient's lower extremities that would require reassessment (Crutchfield et al.; col. 19, lines 50-67) referring patient having ulcers, pain, or gangrene at the time of "no indication for operation" assessment for reassessment (Crutchfield et al.; col. 09, lines 50-67), referring patients classified as “no indication for operation” that develop ulcers, pair and/or gangrene to the vascular surgery facility for reassessment (Crutchfield et al.; col. 09, lines 50-67), reassessing the referred patient at the vascular surgery facility against medically accepted criteria as “no indication for operation" or “clinical indication for operation” (Crutchfield et al.; col. 19, lines 50-67 and col. 20, lines 21-40), transmitting the reassessment of “no indication for operation” or “clinical indication for operation” to the evaluating authority for reevaluation as “no indication for operation" or “clinical indication for operation” (Crutchfield et al.; col. 17, lines 17-28 and lines 65-67, and col. 18, lines 1-14), transmitting the reevaluation to the healthcare faculty with the appropriate medical procedure and regimen (Crutchfield et al.; col. 5, lines 34-57, col. 16, lines 54-67, and col. 17, lines 1-8), treating and monitoring patients classified as "not at risk", " at risk" and

assessed as "no indication for operation" or "clinical indication for operation" at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), providing "not at risk" patient without limb ulcers routing care and precautions at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), providing "not at risk" patient with limb ulcers routine wound care at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), providing "not at risk" patient with limb ulcers periodic reevaluation by the evaluating authority (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67), providing "at risk" patients assessed as "no indication for operation" or "operation not elected by patient" and "clinical indication for operation" patient undergoing revascularization at the vascular surgery facility with intensive would care at the healthcare facility (Crutchfield et al.; col. 46, lines 29-67 and col. 47, lines 23-62), and providing periodic reevaluations of "at risk" patient assessed as "no indication for operation" or "operation not elected by patient" with increased precautions at the healthcare facility (Crutchfield et al.; col. 6, lines 22-39, col. 9, lines 14-52, and col. 19. lines 50-67).

While Crutchfield et al., does not exemplify precisely the patient diagnosis and treatment scenario presented by claim 17 as presently amended, Crutchfield provides the functionality required to enable each of the "assessment" "reassessment" and "treatment" steps defined by claim 17 including the transmission of data and the referral of patients presenting a particular set of symptoms for appropriate treatment. Accordingly, a medical institution and associated staff practicing the Crutchfield et al. invention in the treatment of individuals with vascular disease would achieve the method defined by claim 17 as a result of user selections (i.e., user choices)

made during the course of practicing medicine (i.e., diagnosing and treating patients for vascular disease).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the system and method of Crutchfield et al. to accomplish the method steps defined by claim 17. One of ordinary skill in the art would have been motivated to do so by the desire to assess the vascular health of a patient in order to assess the effects of treatments, risk factors and substances, including therapeutic substances, on blood vessels by measuring various parameters of blood flow in one or more vessels and analyzing the results in a defined manner (Crutchfield et al.; col. 1, lines 25-30).

Response to Remarks//Declaration

[8] The declaration filed on 24 December 2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the Crutchfield et al. (United States Patent #6,699,193) reference.

The evidence submitted is insufficient to establish either conception or a reduction to practice of the invention in this country of a NAFTA or WTO member country prior to the effective date of the Crutchfield et al. reference. Applicant's declaration consists of a "Letter of Agreement" between HealthHelp, Inc. and Tri-Med Management, Inc. The letter includes a general working arrangement between the two parties with regard to a joint interest designated as the Beverly Nursing Homes. Applicant's declaration further includes supportive documentation that serves to clarify the state of the art at the time of the invention with regard to noninvasive examination and study of peripheral vascular disease. The letter and supportive references fail to include substantive evidence of the existence of the claimed invention directed to "classification and management system for patients with lower extremity arterial occlusive disease..." at the time of the "Letter of Agreement".

Applicant's remaining remarks are moot in view of withdrawal of previous rejections under 35 U.S.C. 101 as set forth previously in the Office Action mailed 24 June 2008.

Conclusion

[9] Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. DAVID RINES whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, GERALD J. O'CONNOR can be reached on 571-272-6787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David Rines/
Examiner, Art Unit 3686